Assembly
California Legislature

ASSEMBLY COMMITTEE ON HEALTH
JIM WOOD, CHAIR
ASSEMBLYMEMBER, SECOND DISTRICT

INFORMATIONAL HEARING

Impact of Rising Drug Costs on Public and Private Payers

Tuesday, February 14, 2017 ♦ 1:30 p.m. – 5:00 p.m.

State Capitol ♦ Room 4202

BACKGROUND

PURPOSE

Many new drug products confer enormous clinical benefits to patients, but the costs associated with some of these therapies may place a financial strain on patients who might face high out-of-pocket costs even if they are insured. In addition, expenditure on prescription drugs contributes to overall health care spending growth and creates pressure on federal and state budgets.

In an effort to understand the factors that lead to unexpected drug price increases and offer meaningful solutions that assure patient access while controlling costs, this Committee is holding a series of informational hearings on prescription drug pricing. The first informational hearing entitled "Understanding the Pharmaceutical Supply Chain: What is Driving Up the Cost of Drugs," was held on October 31, 2016, and provided a historical perspective on drug pricing, discussed the economics of drug pricing, and included an overview of the pharmaceutical supply chain.

This second hearing will focus on the impact of prescription drug costs to public and private payers and how this influences the total cost of health care delivery in California. This hearing will explore how the public and private sectors obtain prescription drugs, discuss trends in drug pricing, develop formularies, and various steps that payers are utilizing to address the escalating prices of prescriptions drugs.

BACKGROUND

The rising cost of prescription medicines is putting pressure on public and family budgets in the United States. Expenditures on prescription drugs are projected to continue to rise faster than overall health care spending. According to a recently released U.S. Senate Committee Report on Prescription Drug Prices[1], this year alone, Americans are expected to spend more than $328 billion on prescription drugs. Of this amount, individuals will pay about $50 billion out-of-pocket. The federal government will pick up another $126 billion in payments through Medicare, Medicaid, the Department of Veterans Affairs, and

[1] https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf.

other government programs. These price increases affect all Americans, whether they take prescription drugs or not, as taxpayers shoulder a substantial portion of the cost of federal health care programs.

The private sector and specifically, insurance companies, have also been burdened by sudden price spikes and have sought ways to protect themselves from high prices while providing coverage. In response, they have raised deductibles, increased monthly premiums, transferred high-cost drugs to more expensive tiers, and imposed or increased copays. [2]

Impact on State Programs

Typically, the state pays for prescription drugs under programs that provide health care or health insurance to certain state populations. For example, the state pays for prescription drugs through the health care coverage it provides to the state's low-income residents through the Medi-Cal program and to current and retired state employees. The state also provides and pays for the health care of prison inmates, including the cost of their prescription drugs.

In some cases, the state purchases prescription drugs directly from drug manufacturers and in other cases, the state pays for prescription drugs even though it is not the direct purchaser of them. For example, the state reimburses retail pharmacies for the cost of prescription drugs purchased by the pharmacies and dispensed to individuals enrolled in certain state programs.

Medi-Cal Prescription Drug Benefit

The California Medical Assistance Program (Medi-Cal), administered by the Department of Health Care Services (DHCS), is California's Medicaid program that serves low-income families with children, seniors and persons with disabilities, low-income adults, and pregnant women. As part of the Affordable Care Act, the state expanded Medi-Cal eligibility to include adults without minor children with income below 138% of the federal poverty level.

Medi-Cal provides access to a comprehensive range of drug classes through its fee-for-service (FFS) and managed care delivery systems. Drugs for the treatment of HIV/AIDS, mental illness, including antipsychotic medications, and alcohol and drug abuse are generally "carved out" of the managed care benefit package and are covered through Medi-Cal FFS. Additionally, each Medi-Cal managed care plan must cover and ensure the provision of all prescribed drugs and medically necessary pharmaceutical services.

Medi-Cal FFS beneficiaries may receive up to six dispensed prescriptions within a month without obtaining a prior authorization. If a prescriber determines that a beneficiary's condition requires more than six prescriptions to be dispensed within a month, the prescriber, or pharmacist filling the prescription, may request a waiver of the six-prescription per month limit, by submitting a Treatment Authorization Request (TAR) which is reviewed based on medical necessity.

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[2] https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf.

In 2015-16, Medi-Cal spent over $3.7 billion on outpatient prescription drugs, which represents 4.2% of the DHCS $87 billion 2015-16 Budget. The Governor's 2017-18 Budget estimates that pharmacy FFS spending (including prescribed drugs, medical supplies, and durable medical equipment) will be over $3.89 billion or 3.6% of the DHCS $102.6 billion Medi-Cal budget. These amounts do not include expenditures on prescription drugs made by Medi-Cal managed care plans.

Medi-Cal's Contract Drug List. Medi-Cal has a formulary called the "Medi-Cal Contract Drug List" (CDL). California's CDL is broad and includes psychotherapeutic drugs. Drugs on this list generally do not require prior authorization. For a drug to be placed on the CDL, DHCS staff reviews the drug's efficacy, safety, misuse potential, essential need, and cost. As part of this review, staff might meet with the manufacturer to discuss the drug's therapeutic value or negotiate any supplemental rebates. Drugs that are not on the CDL are still available to Medi-Cal beneficiaries through a prior authorization or TAR. Also, if a drug is being used beyond a restriction listed on the CDL, a TAR may be required.

Medicaid Drug Rebate Program

Section 1927 of the Social Security Act, added by the Omnibus Budget Reconciliation Act of 1990, requires drug manufacturers to sign rebate agreements with the Centers for Medicare and Medicaid Services (CMS) or forego coverage of their drugs by state Medicaid programs. The Medicaid Drug Rebate Program is a program that includes CMS, state Medicaid Agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. The program requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. Approximately 600 drug manufacturers currently participate in the rebate program.

The amount of rebate due for each unit of a drug is based on statutory formulas. For most drugs, the federal rebate is the greater of 23.1% of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban based on launch date and current quarter AMP. The rebates are paid to the states, based on their utilization of the manufacturers' covered drugs, and shared with the federal government.

Aside from federally mandated rebates, California also introduced one of the nation's first programs to require drug manufacturers to pay state-negotiated supplemental rebates, in order for a drug to be on a CDL. According to DHCS, the supplemental rebates allow the state's Medi-Cal drug prices to be somewhat lower that typical Medicaid prices and closer to or below the 340B prices for some drugs. State supplemental drug rebates are negotiated by DHCS with drug manufacturers to provide additional drug rebates over and above federal rebate levels. DHCS anticipates receiving $71.6 million in state supplemental rebates in the Governor's 2017-18 budget.

In 2015-16, California collected a total of $4.081 billion in rebates, of which over $3.8 billion were federal rebates (for FFS, County Organized Health System plan, and Managed Care Organization

(MCO) plan utilization and state rebates (excluding MCO plan drug utilization) amounted to over $206 million. Federal Medicaid rebates are projected to be over $3.2 billion in 2017-18, of which over $1 billion is General Fund.

340B Drug Pricing Program

Section 340B of the Public Health Service Act, commonly referred to as the 340B Drug Pricing Program, allows certain hospitals and other health care providers ("covered entities") to obtain discounted prices on "covered outpatient drugs" (prescription drugs and biologics other than vaccines) from drug manufacturers. Manufacturers must offer 340B discounts to covered entities to have their drugs covered under Medicaid. The intent of the 340B program is to allow certain providers to stretch scarce federal resources as far as possible to provide more care to more patients. The Health Resources and Services Administration (HRSA), which manages the program, calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug. To be eligible for 340B discounted prices, a covered outpatient drug must be provided by a covered entity to its patients.

Several types of hospitals as well as clinics that receive certain federal grants from the U.S. Department of Health and Human Services, like federally qualified health centers and Ryan White grantees, may enroll in the program as covered entities. Eligible hospitals include disproportionate share hospitals (DSHs), critical access hospitals (CAHs), rural referral centers, sole community hospitals, children's hospitals, and freestanding cancer hospitals. Each eligible hospital must be owned by a state or local government, be a public or nonprofit hospital that is formally delegated governmental powers by a state or local government, or be a nonprofit hospital under contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid. Each type of eligible hospital except for CAHs must have a minimum DHSs adjustment percentage (which is based on the share of a hospital's inpatients who are Medicaid and low-income Medicare patients). HRSA's Website indicates that there are 3,705 covered entities in California.

In a 2015 report to Congress by the Medicare Payment Advisory Commission (MEDPAC), HRSA estimates that covered entities saved $3.8 billion on outpatient drugs in fiscal year 2013. This MEDPAC report also states that although the ceiling prices are proprietary, it estimated that, on average, hospitals in the 340B program receive a minimum discount of 22.5% of the average sales price for drugs.

CalPERS

State employees and many local government employees receive health insurance benefits through the California Public Employees' Retirement System (CalPERS). CalPERS annually negotiates rates with health maintenance organizations (HMOs) and sets preferred provider organizations (PPOs) premiums. The costs of drug coverage are included in these annual rate negotiations. In its 2015 Legislative Report, CalPERS described pharmacy trends and projected costs contributing significantly to the overall rates for the 2016 plan year. As a percentage of the overall rate increases for both the HMO and PPOs, about 45% is attributed to pharmacy; approximately 20% of the total pharmacy spending

was attributable to each carrier's top 10 drugs. The balance is attributed to medical expenses, Affordable Care Act fees, and administrative fees. Additionally, a September 2016 presentation to the CalPERS Board of Administration (Board) entitled, "Prescription Drugs Utilization and Cost Trends," included an analysis of claims data demonstrating that costs for prescription drugs continue to rise.

The 2015 total prescription drug costs for drugs obtained through mail-order and at retail pharmacies for all CalPERS plans were $2.1 billion, which represented nearly a 10% increase over the costs of $1.9 billion in 2014. The top 10 non-specialty drugs accounted for $213 million spending or 14% of the total non-specialty drug cost in 2015.

Additionally, CalPERS members are also filling more prescriptions. For example, in 2015, 17.33 million prescriptions were filled for CalPERS members, with an average cost (allowed amount) per prescription of $103.10, an annual increase of 6.62%. The average cost (allowed amount) per day supply was $2.17 with an annual increase of 8.5%. From 2010 to 2015, generic dispensing rates increased from 78.9% to 83.7% for Kaiser, from 75.4% to 85% for Blue Shield of California, and from 66.2% to 78.4% for the PPO plan. From 2013 to 2015, generic dispensing rates for the new HMO plans increased from 82.3 to 87.2% for Health Net, from 82.3 to 84.4% for Anthem, from 80 to 84.6% for Sharp, and from 83 to 85.3% for United Health Care. As more prescriptions are filled, member cost share is also increasing. According to CalPERS, the member cost share for all prescriptions was 8.55%. Member cost share for generics was 16.72%, non-specialty multi-source brand was 7.76%, non-specialty single-source brand was 5.07%, and specialty was 1%. In comparison, the 2014 national average member cost share for all prescriptions for large employers was 20.4%. The 2014 national average member cost share for specialty drugs was 15.1%.

Specialty Prescription Drug Statistics. Specialty pharmaceuticals are a rapidly growing share of total drug expenditures by public and private health plans. These drugs, typically used to treat chronic, serious, or life-threatening conditions, such as cancer, rheumatoid arthritis, growth hormone deficiency, hepatitis C and multiple sclerosis, are often priced much higher than traditional drugs. Total costs can be in the thousands of dollars a month and can exceed $100,000 a year for some products. There are usually few if any low-cost generic equivalents.[3] For its 2015 total prescription drug costs, CalPERS reported that specialty drugs accounted for 28.8% ($587 million) of the total prescription drug costs. Specialty prescription drug cost trends from 2012 to 2015 demonstrated a sharp increase from $270 million to $587 million. Although specialty drug prescriptions represented only 0.89% of all prescriptions in 2015, specialty drug allowed amounts accounted for 28.8% of total CalPERS drug costs. In comparison, Express Scripts reported that specialty drugs accounted for 37.7% of total U.S. drug spend in 2015. The top 10 specialty drugs accounted for $329 million spending or 56% of the total specialty drug cost in 2015.

[3] http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_103.pdf.

CalPERS PBM. To improve its ability to deal with the high cost of prescription drugs, CalPERS sought proposals from pharmacy benefit managers (PBMs) committed to developing clinically sound pharmacy benefit management strategies to combat rapidly increasing drug costs while maintaining member choice and healthcare quality. In May 2016, the CalPERS Board approved a five year PBM contract of nearly $5 billion with OptumRx,s an affiliate of UnitedHealth Group. The five year CalPERS contract covers pharmacy benefits for members enrolled in the CalPERS self-funded PERS Select, PERS Choice, and PERSCare PPO health plans. The contract also covers those enrolled in the Anthem Blue Cross, HealthNet, Sharp, and United Healthcare HMO plans. In total, the contract includes prescription drug benefits for nearly 486,000 members and their dependents.

CalPERS is working with OptumRx to implement drug strategies that encourage clinically appropriate prescribing and lowering net cost without sacrificing clinical outcomes, including step therapy options that offer significant savings to both CalPERS and members. The new PBM contract allows CalPERS the opportunity for increased transparency into the PBM pharmaceutical agreements and obtains a more cost-effective means of dispensing pharmaceuticals while exploring tactics that better influence physician practice to evidence-based medicine and consumer pharmaceutical choices. Although CalPERS is seeking to obtain more cost-effective and efficient services as a result of this new agreement, it is unclear what impact this will have on pharmaceutical prices, which are anticipated to increase over the next five years.

Department of General Services

Please see the Legislative Analyst's Office February 2017 report titled, "Department of General Services' Efforts to Control State Prescription Drug Costs."

Impact on Private Payers

In addition to the burden on government programs, prescription drug costs are one of the leading contributors to health spending growth in the private sector, including employers, health plans, and hospitals.

Employer Groups

According to data from the Kaiser Family Foundation (KFF), 49% of the U.S. was insured by employer-sponsored coverage either through their own job or as a dependent in the same household in 2015. In California, this number was 45%. Similar to other purchasers and payers of health benefits, prescription drug spending for employer-sponsored coverage is also showing an upward trend. For example, from 2004 to 2013 the average retail drug spending in employer plans held relatively steady, ranging from $909 per enrollee in 2004 to $947 in 2013 (adjusted for inflation), but grew to 13.0% in 2014 to $1,053 per enrollee.[4] Though drug spending trends in large employer plans generally mirror

[4] Cynthia Cox, Anthony Damico, Gary Claxton, Larry Levitt, *Examining high prescription drug spending for people with employer sponsored health insurance*, October 27, 2016 http://www.healthsystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/.

national trends, retail prescription drug spending does, however, represent a larger share of total employer insurance benefits (21%) than retail drugs represent as a share of total national health spending (10%). The growth in prescription drug spending may have a relatively large effect on employer-sponsored health insurance premiums. Over time, the share of people with high retail drug spending (exceeding $5,000 annually, including amounts paid by insurance and out-of-pocket) has increased from 1.6% in 2004 to 3.9% in 2014, as has the share of people with exceptionally high drug spending (exceeding $20,000) from 0.1% to 0.8% over the same period. Workers and their family members who are older, and women tend to have higher drug spending. People diagnosed with certain conditions, particularly diseases of the blood (like hemophilia), cancer, digestive diseases, circulatory conditions, and endocrine disorders are also more likely to have high drug spending.

Employers continue to pursue a range of cost-cutting strategies with an emphasis on shifting more responsibility onto workers. Over the past decade, out-of-pocket spending for prescription drugs has shifted from being almost entirely paid through copayments, toward significantly more deductible and coinsurance spending. In 2014, 24% of out-of-pocket prescription drug expenses were paid through deductibles, compared to just 4% in 2004. Similarly, 20% of out-of-pocket drug expenses were paid through coinsurance spending in 2014, compared to just 3% in 2004. These higher deductible and coinsurance payments relative to copayments reflect a general trend of higher deductibles in employer plans, as well as greater use of tiered formularies. Enrollees may be more sensitive to the actual price of health care with deductibles and coinsurance than they are with copays, which are flat dollar amounts. Additionally, copays require smaller periodic payments that may add up over time, while a deductible may need to be met at once, potentially causing affordability challenges.

Insurance Companies

Insurance companies exist, in theory, to protect people from unexpected high costs of healthcare. Enrollees pay a monthly premium that goes into a large "pool" and individuals draw from that pool to pay for a healthcare expense. In the case of drugs, insurance companies often work with PBMs that further pool consumers together to negotiate large-volume discounts from drug companies to generate savings for the covered individual. The only way left for insurers to provide coverage for a drug but maintain their profit margins is to reduce how much insurance coverage—and thus protection from high prices—they offer to a consumer. This can happen in at least one of four ways: by raising the deductible; by increasing monthly premiums; by increasing the copay; by putting drugs into more expensive tiers; or, by making the enrollee pay coinsurance, where the individual pays a percentage of the medication's cost; usually one-third or more. [5]

Access to affordable prescription drugs is an important aspect of the health care system. Prior to 2014, health plans under the Department of Managed Health Care, including the essential health benefits (EHBs) benchmark, were subject to extensive and detailed statutory and regulatory standards affecting coverage of prescription drugs, including the requirement to

[5] Consumer Reports, Is There a Cure for High Drug Prices? July 29, 2016, http://www.consumerreports.org/drugs/cure-for-high-drug-prices.

cover all medically necessary drugs; standards for developing and administering health plan drug formularies and drug substitutions; provisions affecting enrollee cost sharing; and, permissible and prohibited limitations and exclusions. Through the enactment of EHBs for California, many of these prescription drug coverage requirements were, for the first time, applied to health insurance coverage under the California Department of Insurance.[6] EHBs are a set of 10 categories of services health plans and policies must cover under the Affordable Care Act. These include doctors' services, inpatient and outpatient hospital care, prescription drug coverage, pregnancy and childbirth, mental health services, and more. Some plans cover more services.

Current law requires most health insurers and health plans to limit enrollee out-of-pocket expenses (the most an enrollee would have to spend for covered services in a year and after reaching this amount, the insurance company pays 100% for covered services) for EHBs, including prescription drugs. Payment for covered health benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. The enrollee cost share is the portion that must be paid out-of-pocket directly to the provider, generally at the time of treatment. Common cost sharing mechanisms include copayments (fixed amount the enrollee pays for a covered health care service after paying the deductible), coinsurance (percentage of costs of a covered health care service the individual pays after paying the deductible), and/or deductibles (amount the individual pays for covered health care services before the insurance plan starts to pay). Additionally, health insurers and health plans often use prescription drug formularies with prescription drug tiers. Drug formularies typically have one to four tiers, with the first tier including generic and low cost drugs and the fourth tier including specialty and high-cost drugs. Typically, enrollee cost sharing increases for drugs in the upper tiers. AB 339 (Gordon), Chapter 619, Statutes of 2015, further describes prescription drug coverage for specified products by requiring health plans and health insurers that provide coverage for outpatient prescription drugs to have formularies that do not discourage the enrollment of individuals with health conditions. AB 339 places in state law, federal requirements related to pharmacy and therapeutics committees, access to in-network retail pharmacies, standardized formulary requirements, formulary tier requirements similar to those required of health plans and insurers participating in Covered California, and copayment caps of $250 and $500 for a supply of up to 30 days for an individual prescription.

Hospitals

Most healthcare spending is for care provided by hospitals and physicians. According to the National Health Expenditure Accounts, in 2015 hospital care spending accounted for 32% of overall health spending. Additionally, spending for hospital care increased in 2015 at 5.6% growth for a total of $1 trillion in spending, compared to 4.6% growth in 2014. A 2016 hospital report entitled "Trends in

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[6] Catherine I. Starner, G. Caleb Alexander, Kevin Bowen, Yang Qiu, Peter J. Wickersham and Patrick P. Gleason, Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve, Adherence At The Risk Of Increasing Premiums, *Health Affairs* 33, no.10 (2014):1761-1769.

Hospital Inpatient Drug Costs: Issues and Challenges." pointed out that hospitals bear a heavy financial burden when the cost of drugs increases. For example, between fiscal year (FY) 2013 and FY 2015, inpatient drug spending increased an average 23.4% annually, and on a per admission basis, by 38.7%. More than 90% of responding hospitals reported that recent inpatient drug price increases had a moderate or severe effect on their ability to manage the overall cost of patient care, with one-third of the respondents indicating that the impact was severe. Many of the sampled drugs that experienced substantial unit price increases in calendar year (CY) 2014 and CY 2015 were high volume drugs.

Hospitals are significant purchasers of prescription drugs, such as anesthesia and antibiotics to prevent infections during surgery. They also treat patients suffering the repercussions of being unable to afford or otherwise access their medications, often when these individuals return through the emergency department. The way in which hospitals are reimbursed compounds the impact of increasing drug costs. Most hospitals are not directly reimbursed for the drugs they purchase used in the inpatient setting. Instead, they generally receive a single payment for all non-physician services, including drugs provided during an inpatient stay or, less commonly, each inpatient day (per diem). For example, Medicare, which accounts for a significant source of payments to hospitals for inpatient services nationally, uses a reimbursement system that cannot keep pace with changes in drug prices. Some commercial and other payers either use the Medicare payment model, called the Inpatient Prospective Payment System, or pay directly based on the Medicare rate, e.g., as a percentage of Medicare reimbursement. When reimbursement rates cannot keep up with input costs, such as drugs, hospitals must absorb the excess.

CONCLUSION

California tops the nation in retail drug spending. According to the latest data available from KFF, in 2015 there were 459 million prescriptions filled at retail pharmacies in California. This accounted for over $35.2 billion in retail pharmacy sales (which includes sales at independent pharmacies, retail (chain) pharmacies, food stores, and mass merchandisers). With this figure, California leads the country in retail sales at 12.3%, followed by New York at 7.8% ($22.3 billion), and Texas at 6.6% ($18.9 billion). Numerous trends threaten to drive the costs of medicines even higher: more extremely expensive specialty drugs, monopoly pricing of old drugs, and an aging population. This level of spending is putting pressure not just on state budgets but also on private payers. While the lifesaving value of pharmaceuticals cannot be denied, policymakers are facing a growing sense of urgency to find options to tackle rising drug costs while balancing the equally important interests of maintaining access and containing costs. Arguably, the most effective strategy requires modifying federal laws and regulations, but lawmakers can also consider strategies to lowering drugs costs, including greater transparency of the financial flows within the drug supply chain, evidence-based formularies, and limiting the use of prescription drug coupons that increase the costs of government and private medical insurance.